

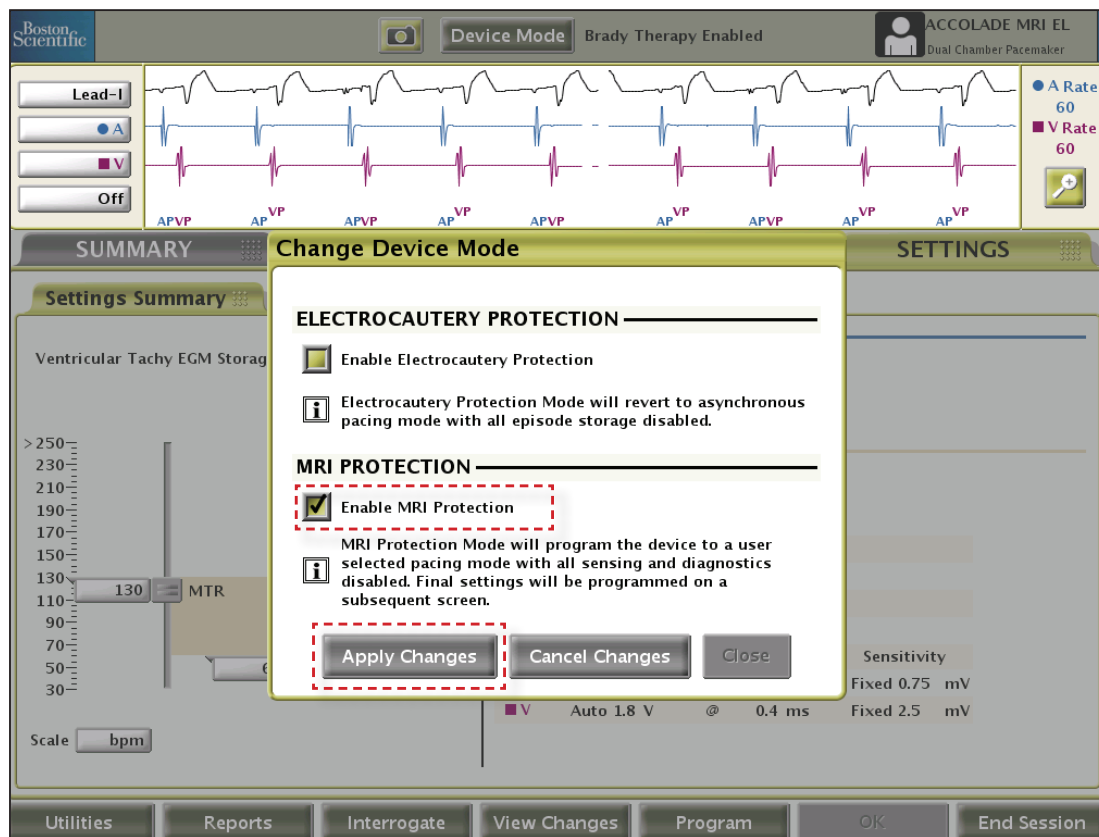
IMAGEREADY™
MR-Conditional Pacing System

Programming Manual for MRI Protection Mode



INGEVITY™ MRI Pacing Lead
ACCOLADE™ MRI Pacemakers
ESSENTIO™ MRI Pacemakers

Please refer to the MRI Technical Guide:
ImageReady™ MR -Pacing System as the system is
designated as MR-conditional in accordance with specific conditions.



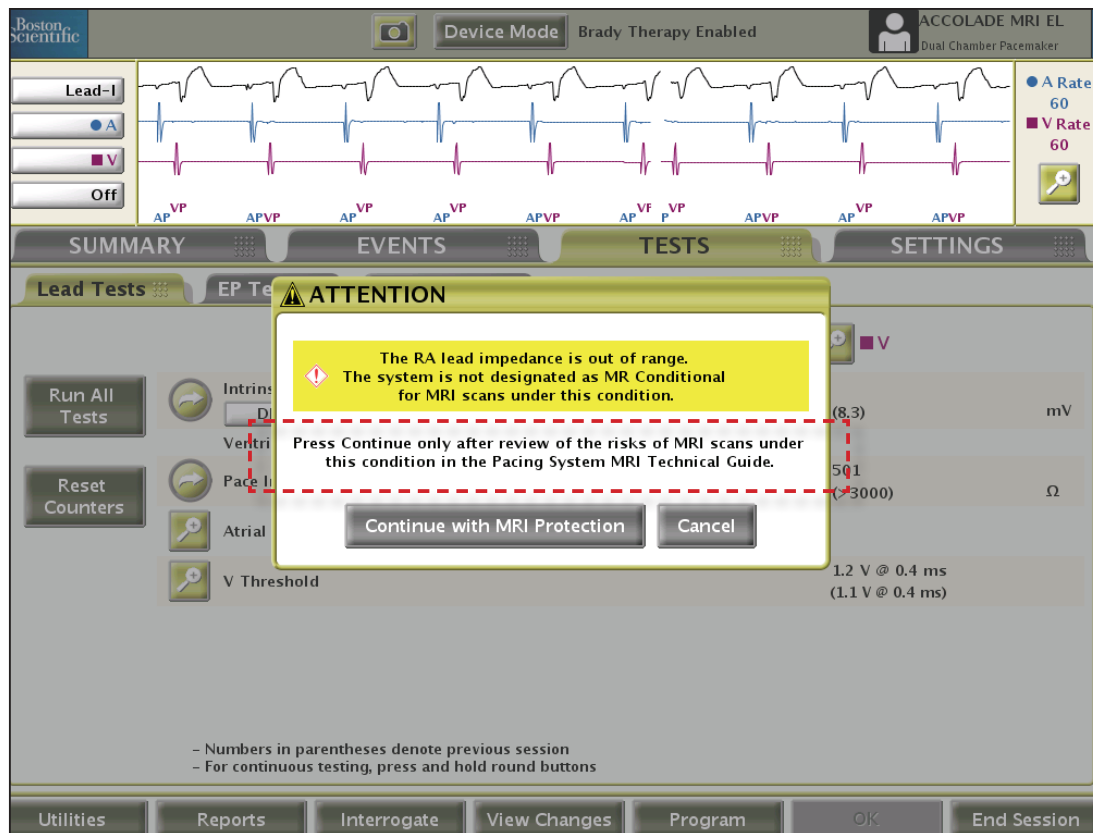
Boston Scientific's ImageReady™ MR-Conditional Pacing System has been created specifically as a system for use with MRI scans when performed under the Conditions of Use.

The Cardiology and Radiology Checklists are included as references at the end of this manual.

Additionally, an MRI Protection Mode has been created for use during an MRI scan. Use the Boston Scientific Programmer to program the pulse generator entry into MRI Protection Mode.

Select Device Mode, next select Enable MRI Protection and then Apply Changes.

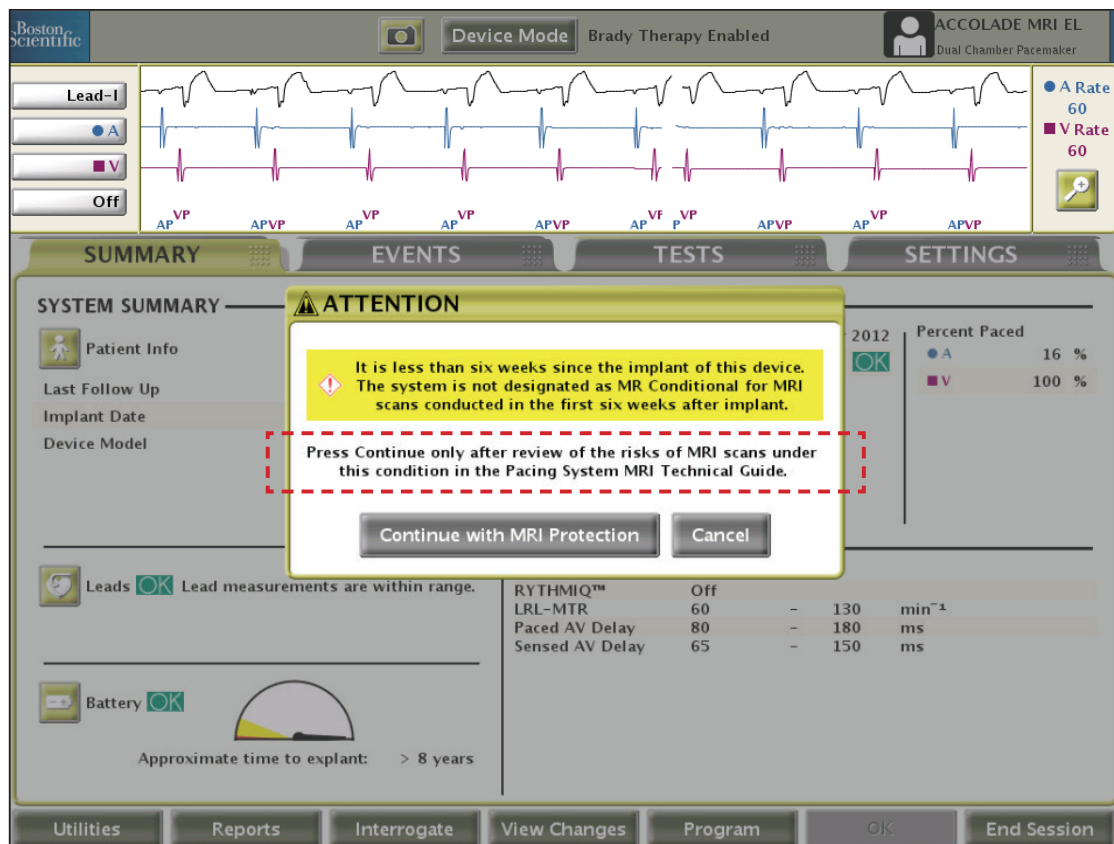
Once "Apply Changes" is selected, 2 checks are automatically performed: a lead impedance test in all chambers and a calculation of the time since implant.



The ImageReady™ MR-Conditional System is designed with several built-in safety reminders, viewable as Attention Screens.

If the impedance value for any of the leads is outside the programmed normal range, a dialog recommending review of the associated risks if the user chooses to proceed is displayed.

The dialog provides the option to either continue with MRI Protection or Cancel.

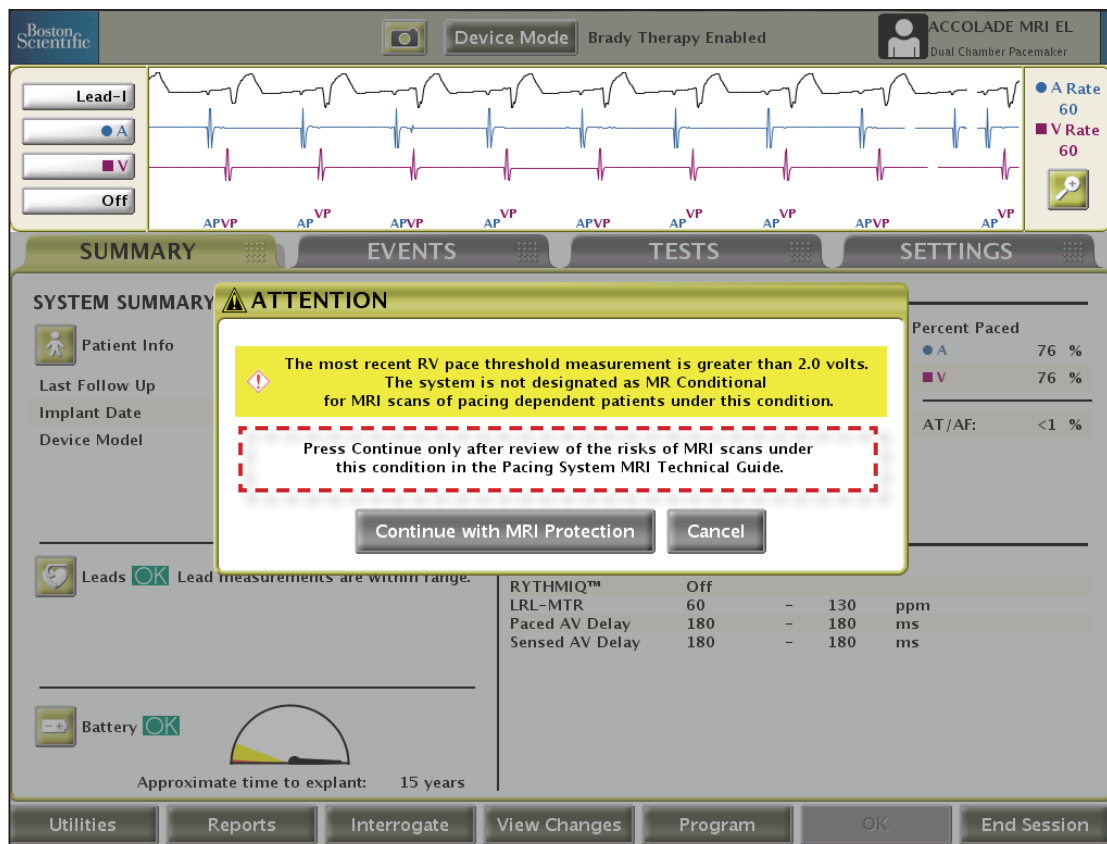


The programmer calculates the time since implant based on when the device was taken out of storage mode.

If the calculated time is < 6 weeks, a dialog is displayed recommending reviewing the associated risks.

The dialog provides the option to either continue with MRI Protection or Cancel.

Note: If the programmer clock is not set to the correct time and date, this determination will not be accurate.



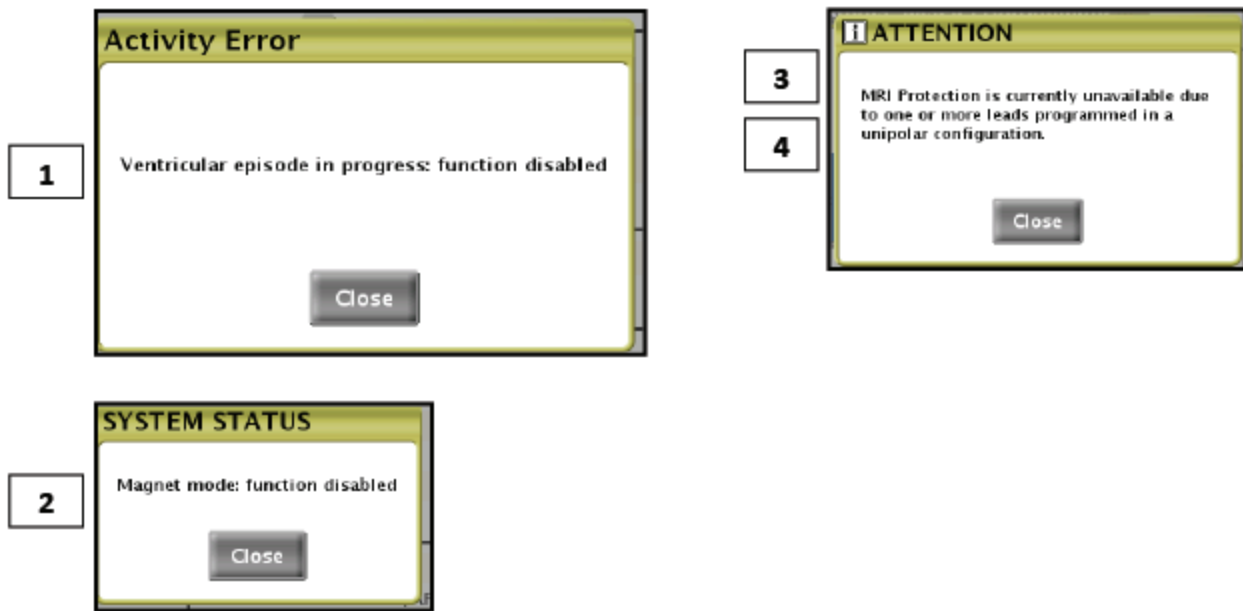
The system will automatically assess the most recent pacing threshold(s).

If the threshold is > 2.0 V, an attention message appears on the screen advising the user to review risks of proceeding.

A Condition of Use applicable to pace-dependent patients is pacing thresholds are less than or equal to 2.0 V.

Thresholds greater than 2.0 V may result in an insufficient safety margin and failure to capture in MRI Protection Mode.

The most recent results of either the ambulatory PaceSafe™ tests or commanded tests are used.



There are certain conditions in the device and/or system that will cause a user request to enter MRI Protection Mode to be rejected.

There will be no option to continue with MRI Protection programming.

These include:

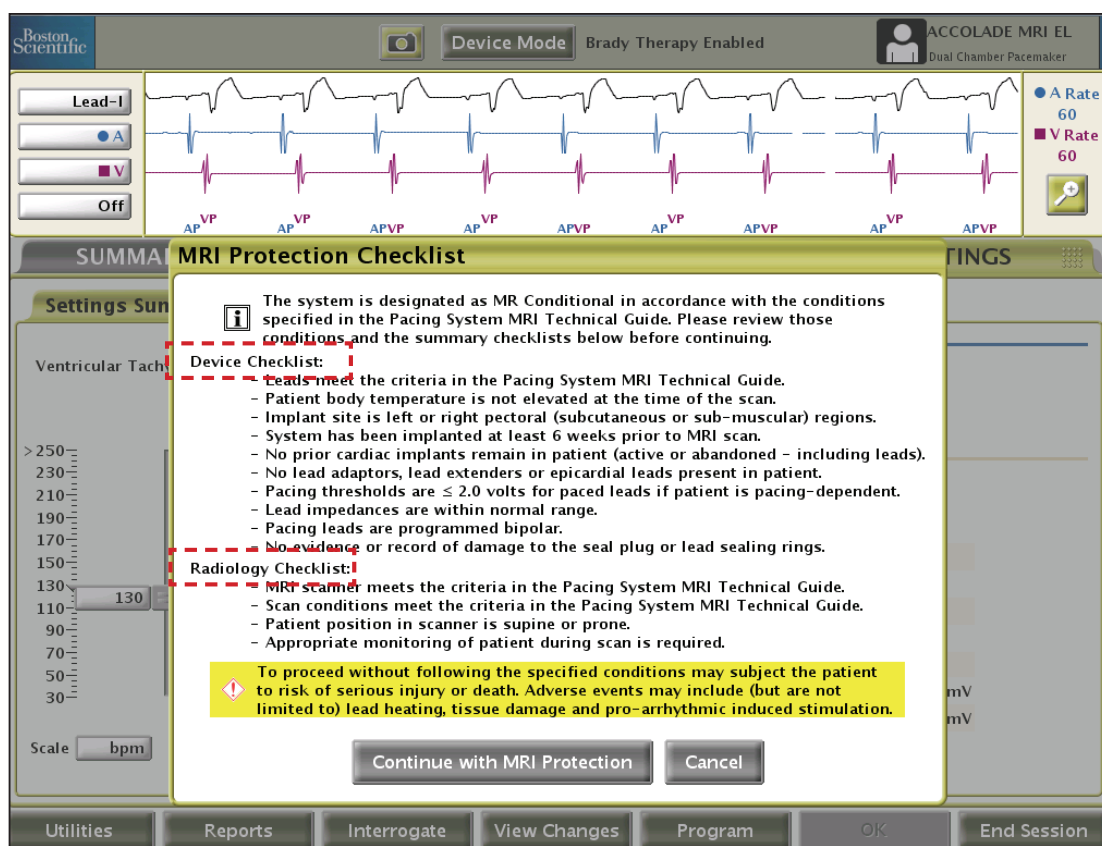
1. A ventricular episode as detected and recognized by the device is in progress. MRI Protection mode will not be available.
2. Magnet presence is detected by the magnet sensor. The function of enabling MRI Protection mode is disabled until the magnet is removed.
3. A Unipolar pacing configuration is programmed in chamber(s) where pacing will occur in MRI Protection Mode. One of the Conditions for Scanning is a bipolar pacing operation. The device will automatically confirm that the Pacing Lead Configuration is set to bipolar.

Unipolar lead configurations increase the risk of induced voltages in the lead system. Additionally, bipolar ventricular pacing operation is required to support Safety Core operation, if Safety Core is entered from MRI Protection Mode.

4. The user will see the same message if the device is in a STAT PACE mode, which uses unipolar pacing. If any one or more of these conditions are present, a dialog box will appear describing the condition, and MRI Protection Mode cannot be entered.

Other device conditions that will preclude the user from having the option to enter MRI Protection Mode include:

- Battery capacity status is depleted
- Device is in Storage Mode
- Device is in Electrocautery Mode
- Device is in Safety Core operation
- A diagnostic test is in progress
- An EP test is in progress



Upon continuing with entry into MRI Protection Mode, the MRI Protection Checklist screen is displayed which summarizes the conditions that must be met at the time of scanning in order for a patient to be eligible for an MR Conditional Scan.

The Device Checklist is specific to the Cardiologist's assessment of eligibility.

Below this list is the Radiology Checklist, specific to the MRI environment, patient positioning, and patient monitoring.

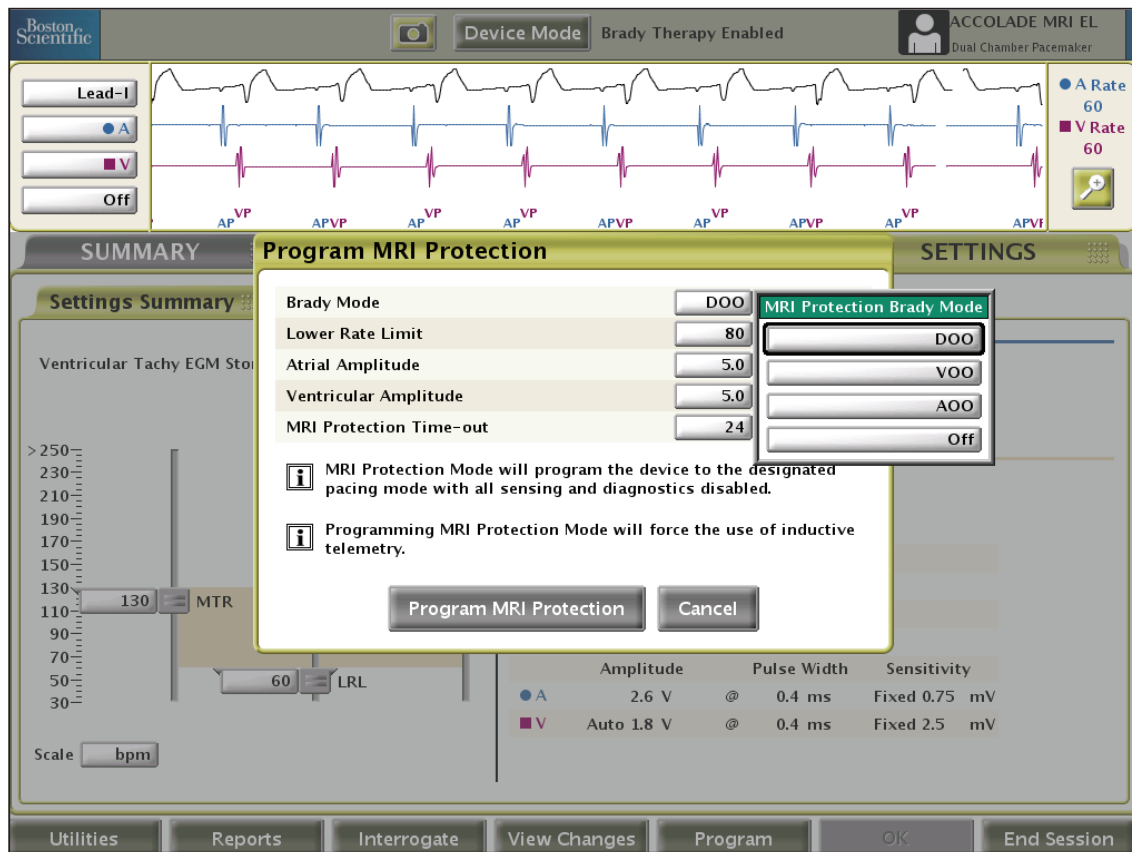
Note: Labeling provides additional Conditions and details regarding the Radiology Checklist.

Appropriate monitoring of the patient includes an external defibrillator and medical personnel skilled in CPR being present during the MRI scan.

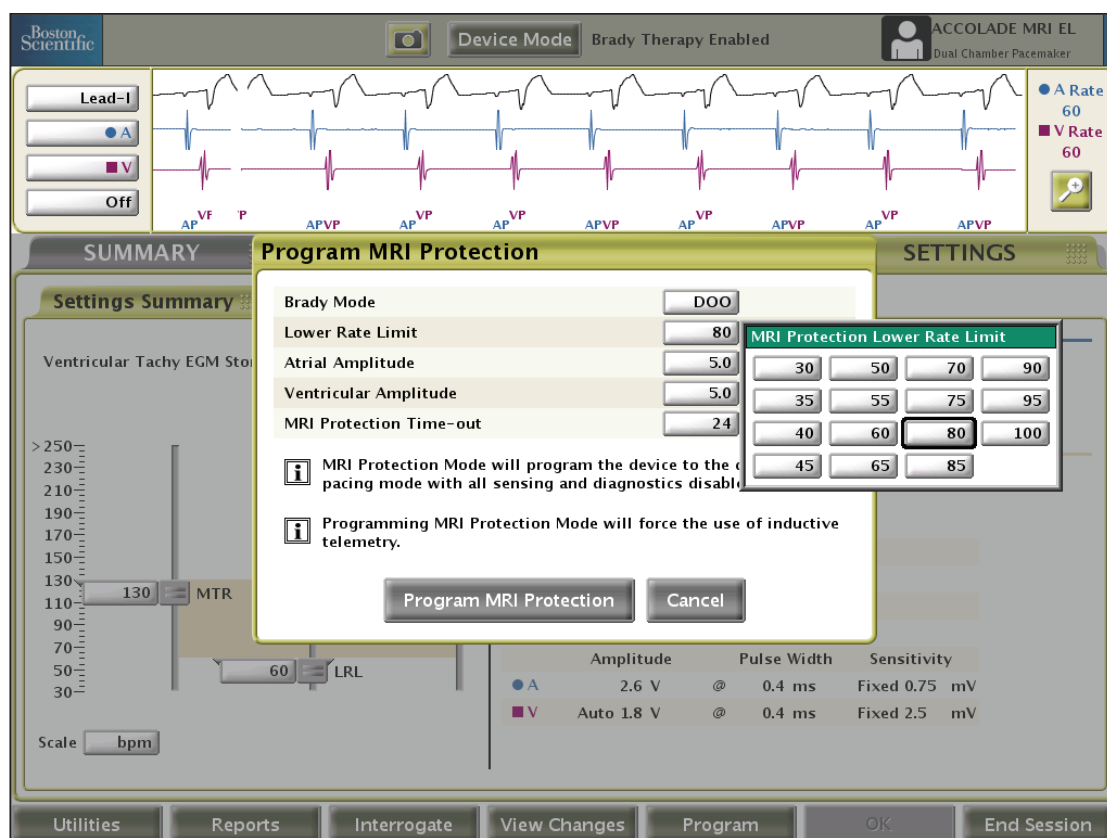
If the Conditions of Use are not met, the Cancel button is selected to return to normal system operation, and the patient does not undergo an MRI scan.

If the Conditions of Use are met, or if the Conditions of Use are not met but the user elects to continue with MRI Protection Mode after reviewing the risks or proceeding, the Continue with MRI Protection button is selected.

As a result, the Program MRI Protection screen is displayed and the user can program the following parameters shown on the next page.

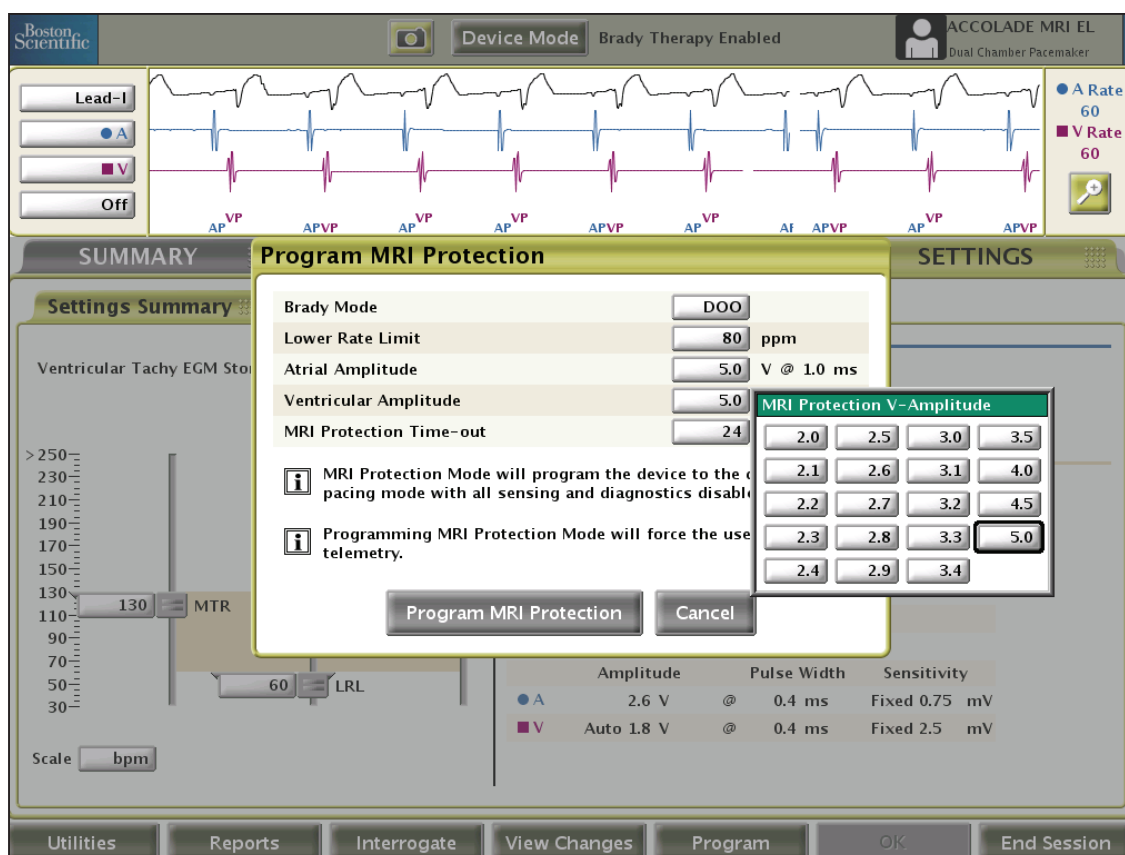


Use the dialog boxes to set the Pacing Mode: DOO, VOO, AOO, or off.



Set the Lower Rate Limit, which is nominally set to 20 beats per minute above the normal mode Lower Rate Limit.

Because MRI Protection Mode pacing is asynchronous, when setting the lower rate limit, the patient's intrinsic rate should be considered to avoid competitive pacing.



Set the Atrial and Ventricular Amplitudes, programmable in normal increments from 2.0-5.0 V.

The pulse generator nominal amplitudes in MRI Protection Mode are set to 5.0 V, providing a minimum two-fold safety margin for patients with a pacing threshold ≤ 2.0 V plus an additional 1.0 V to counteract gradient-induced pace pulse offsets.

Program MRI Protection

Brady Mode	DOO	
Lower Rate Limit	80	min ⁻¹
Atrial Amplitude	5.0	V @ 1.0 ms
Ventricular Amplitude	5.0	V @ 1.0 ms
MRI Protection Time-out	24	h

i MRI Protection Mode will program the device to the designated pacing mode with all sensing and diagnostics disabled.

i Programming MRI Protection Mode will force the use of inductive telemetry.

MRI Protection Time-out

Select the duration of the MRI Protection period (in hours). Selecting Off leaves the PG in MRI Protection Mode until reprogrammed.

Attention: If MRI Protection Time-out is programmed Off, and Brady Mode is Off, patient will not receive pacing until reprogrammed.

Off	24
12	48

Unique to Boston Scientific, a Time-out feature can be programmed to allow automatic exit from MRI Protection Mode after a set number of hours chosen by the user.

MRI Protection Time-out is nominally set to 24 hours, programmable to Off, 12, 24, and 48 hours.

Important to note, if the value is programmed to Off, the device will remain in MRI Protection Mode indefinitely; only a programmer can be used to exit MRI Mode.

If the Time-out feature is set to a value other than Off, the Radiologist verifies that adequate time remains to complete the scan.

After exiting MRI Protection Mode, all parameters are immediately restored to pre-MRI Protection Mode values with two exceptions.

If PaceSafe™ Automatic Capture (RVAC) was programmed on, this feature enters suspension upon entry of the device into MRI Protection Mode.

Upon exit from MRI Protection Mode, the RV pace amplitude is set to 2 times the last capture threshold determined by the RVAC feature before it entered suspension (output is limited to between 3.5 V and 5.0 V).

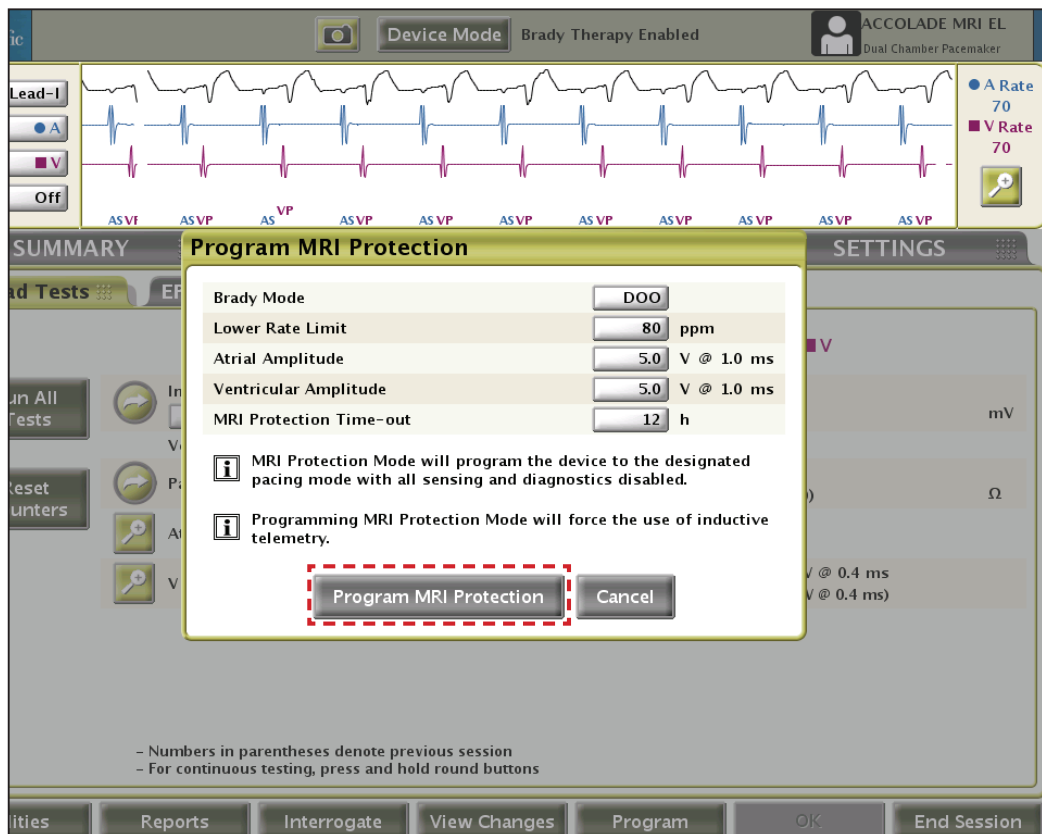
After the next scheduled autothreshold test runs (within the next 21 hours), and is successful, the RV pace amplitude is set to the new capture threshold plus 0.5 V.

Restoration of function of the Minute Ventilation sensor is also delayed upon exit from MRI Protection Mode.

If MV is programmed to On or Passive at the time of entry into MRI Mode, upon exit from the mode, an automatic six-hour calibration of the sensor will begin.

If MV-driven rate response is desired sooner, a manual calibration can be performed.

Please note that if MRI Protection Time-out is programmed Off, and Brady Mode is off, the patient will not receive pacing until the device is manually programmed out of MRI Protection Mode and back to normal operation.



Once all settings have been determined, the user is now ready to enable MRI Protection.

A reminder on the screen states that all sensing and diagnostics will be disabled.

There is an additional message that states programming MRI Protection Mode will force the use of inductive telemetry.

This means that the user must maintain access to the programmer wand, as RF telemetry becomes unavailable during the process of entering MRI Protection Mode.


When the user presses the Program MRI Protection button, the wand must be used from this point forward to complete entry into MRI Protection Mode.



This screen indicates that the device has been successfully programmed into MRI Protection Mode at the settings indicated.

Print a copy of the settings before ending the session.

The report lists the settings in operation during MRI Protection Mode.

	ZOOM @ View™ MRI Protection Settings Report		Report Created 12 Jun 2015
	Date of Birth: N/R N/R N/R Device: ACCOLADE MRI EL L331/417103	Last Office Interrogation: 12 Jun 2015 Implant Date: 1 Mar 2015	

MRI Protection is Programmed MRI Protection Entry Time: 12 Jun 2015 13:51	
MRI Protection Time-out Scheduled Expiration Time:	12 h 13 Jun 2015 01:52
⚠ Patient must be out of MRI scanner before the scheduled expiration time.	

Settings During MRI Protection		
Parameter	Previous Value	MRI Protection Value
Brady Mode	DDD	DDO
Lower Rate Limit	60 ppm	80 ppm
AV Delay	180 - 220 ms	100 ms
Pacing Output:		
Atrial	3.0 V @ 0.4 ms	3.5 V @ 1.0 ms
Ventricular	3.0 V @ 0.4 ms	3.5 V @ 1.0 ms

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ZOOM @ View™ MRI Protection Settings Report		12 Jun 2015 13:52
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Settings During MRI Protection (Continued)		
The following features are disabled during MRI Protection: Ventricular Tachy EGM Storage RV Automatic Capture RA Automatic Threshold Daily diagnostics Magnet detection RF Telemetry		

Leads Data	Pre-MRI Scan Measurement	Measurement Date
Atrial		
Intrinsic Amplitude	4.7 mV	12 Jun 2015 13:30
Pace Impedance	538 Ω	12 Jun 2015 13:51
Pace Threshold	1.3 V @ 0.4 ms	12 Jun 2015 13:33
Ventricular		
Intrinsic Amplitude	8.4 mV	12 Jun 2015 13:30
Pace Impedance	636 Ω	12 Jun 2015 13:51
Pace Threshold	1.3 V @ 0.4 ms	12 Jun 2015 13:32

MRI Protection Checklist The system is designated as MR Conditional in accordance with the conditions specified in the Pacing System MRI Technical Guide. Please review those conditions and the summary checklists below before continuing.
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In this example, the MRI Protection Time-out is programmed to 12 hours.

If the Time-out feature is used, the report includes the time and date when MRI Protection Mode will expire, returning the pulse generator to the pre-MRI Protection Mode settings.

Most recent lead measurements are also listed.

The printed report can be placed in the patient's file and used by Radiology personnel, for example, to confirm that sufficient time remains to complete the MRI scan.

ZOOM 3 View™
MRI Protection Settings Report

12 Jun 2015 13:52


MRI Protection Checklist (Continued)

Device Checklist:

- Leads meet the criteria in the Pacing System MRI Technical Guide.
- Patient body temperature is not elevated at the time of the scan.
- Implant site is left or right pectoral (subcutaneous or sub-muscular) regions.
- System has been implanted at least 6 weeks prior to MRI scan.
- No prior cardiac implants remain in patient (active or abandoned - including leads).
- No lead adaptors, lead extenders or epicardial leads present in patient.
- Pacing thresholds are ≤ 2.0 volts for paced leads if patient is pacing-dependent.
- Lead impedances are within normal range.
- Pacing leads are programmed bipolar.
- No evidence or record of damage to the seal plug or lead sealing rings.

Radiology Checklist:

- MRI scanner meets the criteria in the Pacing System MRI Technical Guide.
- Scan conditions meet the criteria in the Pacing System MRI Technical Guide.
- Patient position in scanner is supine or prone.
- Appropriate monitoring of patient during scan is required.

 To proceed without following the specified conditions may subject the patient to risk of serious injury or death. Adverse events may include (but are not limited to) lead heating, tissue damage and pro-arrhythmic induced stimulation.


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ZOOM 3 View™
MRI Protection Settings Report

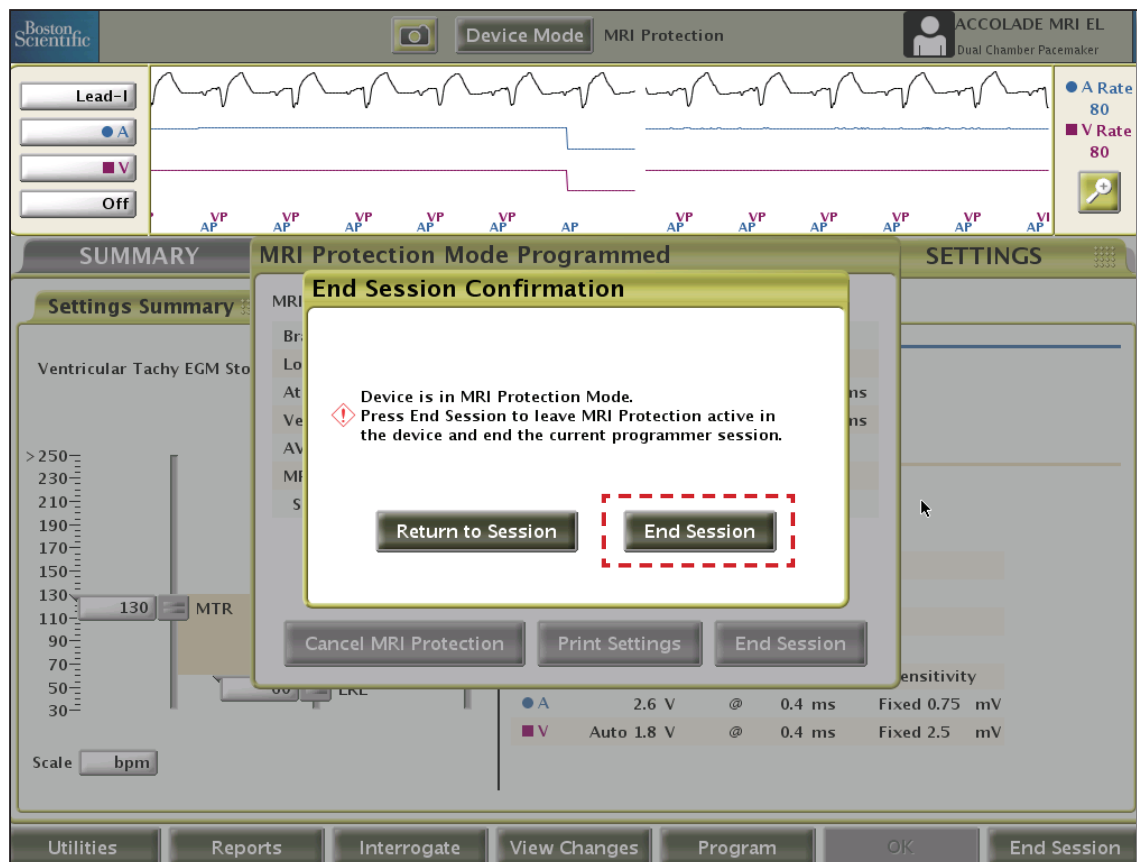
12 Jun 2015 13:52

2869 Software Version: 2.02
L331 Firmware
Version: F_v1.00.00

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Clinician Signature: 

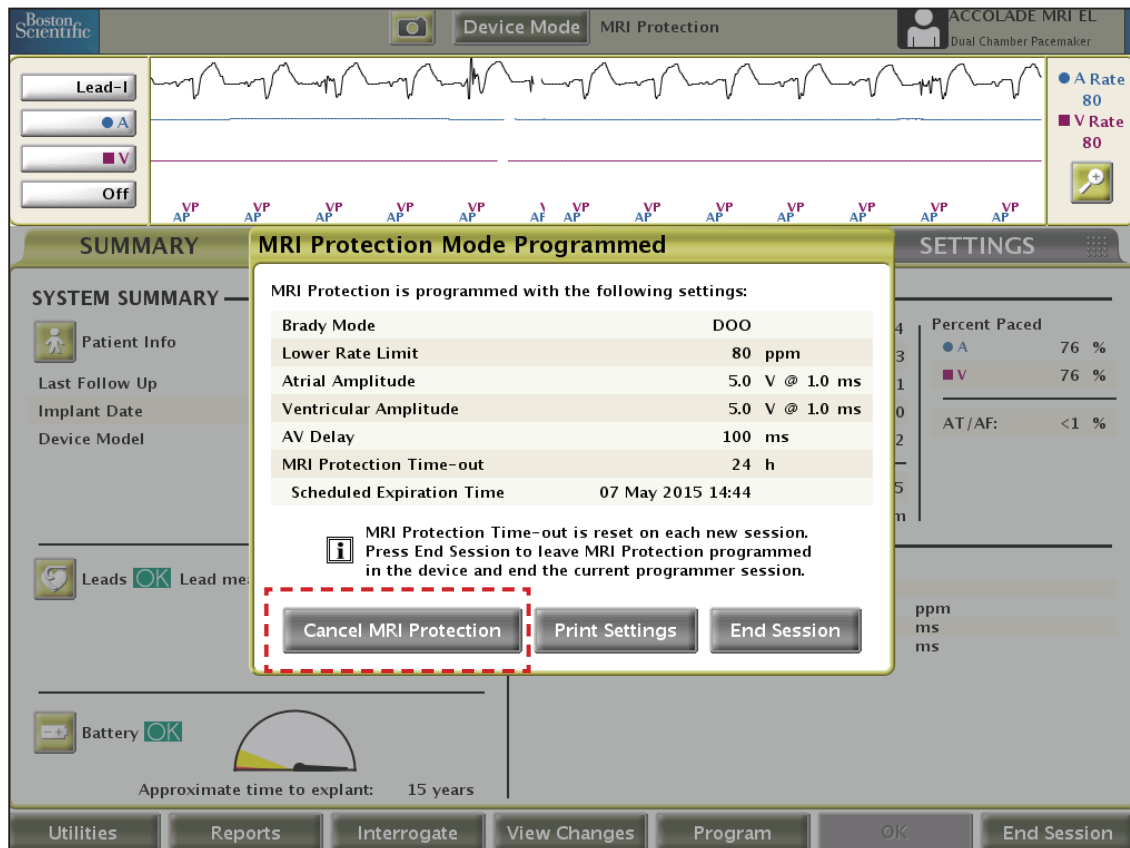
The third page of the report includes both the Device Checklist for Conditions of Scanning and the Radiology Checklist.



Selecting the End Session button will end the current programmer session with the device remaining in MRI Protection Mode.

Most device functions shutdown in MRI Protection Mode, such as:

- PaceSafe™ RV automatic capture
- PaceSafe RA automatic threshold
- Cardiac sensing
- Daily diagnostics (lead impedance, intrinsic amplitude, pace threshold)
- Motion and respiratory sensors
- Magnet detection
- RF telemetry and Remote Monitoring
- Battery voltage monitoring



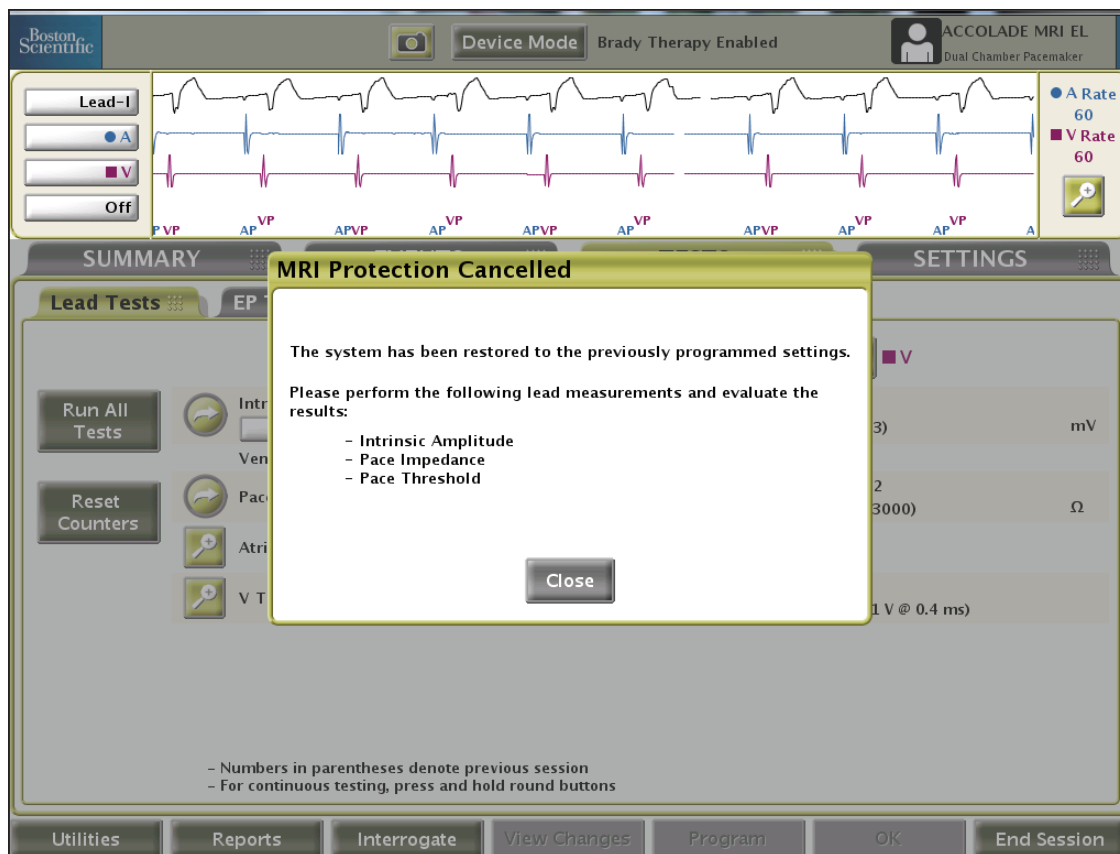
Following the scan and after interrogating the device with the wand, the user will again be presented with this message on the screen.

If the Time-out parameter was programmed to a value other than Off, the device will exit MRI Protection Mode automatically after the selected number of hours, and the system will return to previously programmed settings.

Alternatively, if the Time-out feature is not used (is programmed to Off), the device must be interrogated by the wand to exit MRI Protection Mode.

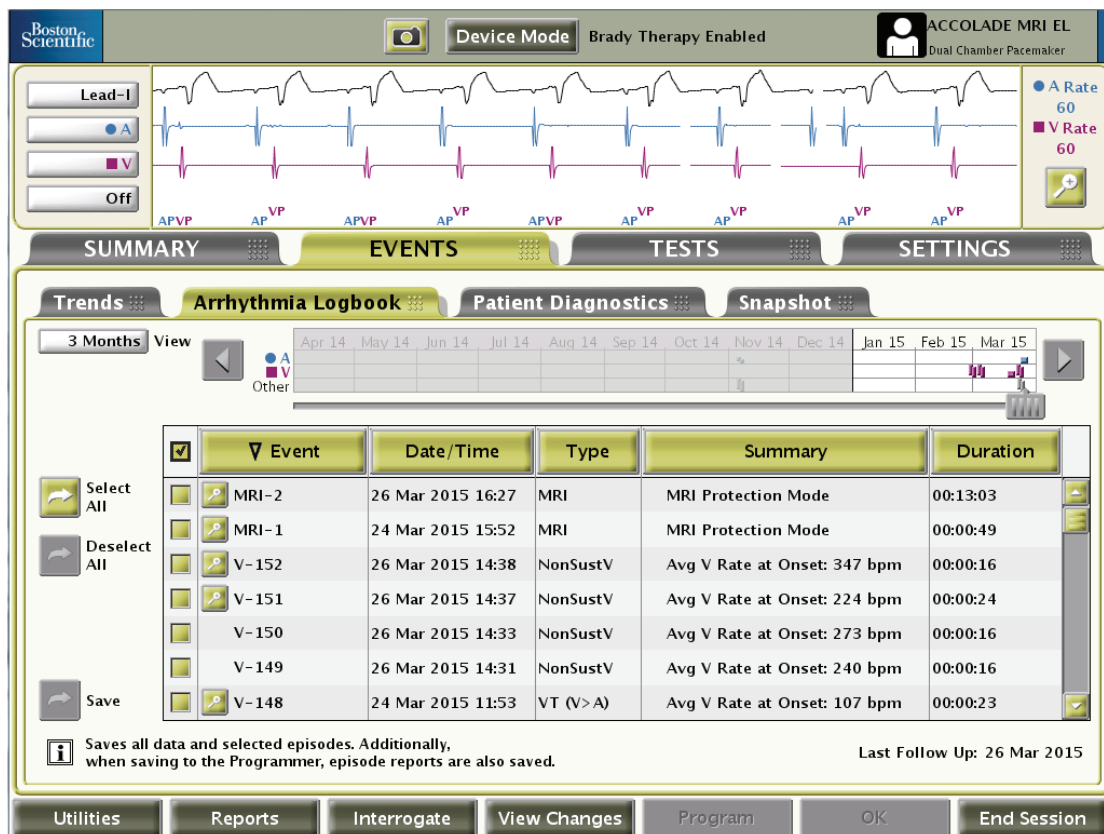
Labeling states: Do not leave the device in MRI Protection Mode any longer than necessary following the scan.

Select the Cancel MRI Protection button.



Following user-initiated cancellation of MRI Protection Mode, the programmer will automatically navigate to the Lead Tests screen and prompt the user to perform the following lead tests:

- Intrinsic amplitude
- Lead impedance
- Pacing threshold



Upon exiting MRI Protection Mode (either timer initiated or manually exited), an Event is stored as an MRI episode and can be printed or saved as an episode report.

The MRI episode can also be viewed in the Arrhythmia Logbook via Remote Patient Monitoring (if available).

The following are additional references:

Boston Scientific MRI Technical Guide: ImageReady™ MR Conditional Pacing System

www.bostonscientific.com/imageready

Boston Scientific MRI Hotline Number: 1.844.427.2674 (1.844.4.BSC.MRI)

Cardiology/Radiology Checklists

Use the following checklists to ensure that patients who have a Boston Scientific pacing system labeled MR-conditional can receive an MR scan safely. Prior to the procedure, please see the full instructions (including warnings/precautions and potential adverse events) in the Boston Scientific ImageReady MR-Conditional Pacing System MRI Technical Guide, or www.BostonScientific.com/imageready or Boston Scientific MRI Hotline 1.844.4.BSC.MRI (1.844.427.2674).

Patient Name: _____ Date of Birth: _____
Pacemaker Model: _____ RV Lead Model: _____ Atrial Lead Model: _____

The following conditions must be met in order for a patient with a Boston Scientific ImageReady MR-Conditional Pacing System to undergo an MRI scan:

For Cardiologists ~ MRI Conditions for Use¹

- Patient is implanted with an ImageReady MR-Conditional Pacing System
- At least six weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR-conditional pacing system
- Pulse-generator implant location restricted to left or right pectoral region
- No cardiac-related implanted devices, components, or accessories present (such as lead adapters or extenders) other than an ImageReady MR-Conditional Pacing System
- No abandoned leads or pulse generators
- No evidence of fractured lead or compromised pulse-generator-lead integrity (impedance out of normal range, or evidence or record of damage to generator seal plug or sealing rings)
- Pacing threshold $\leq 2.0V$ in pace-dependent patients
- Bipolar pacing operation or pacing Off
- Patient does not have elevated body temperature or compromised thermoregulation at time of scan
- Pulse generator in MRI Protection Mode during scan

For Radiologists ~ MRI Conditions for Use¹

- MRI magnet strength of 1.5 T
 - Radio frequency of approximately 64 MHz
 - Spatial gradient no greater than 50 T/m (5,000 G/cm) over the pacing system
- Horizontal, H proton, closed bore scanners only
- Specific Absorption Rate (SAR) limits:
 - INGEVITY™ MRI Pacing Leads: SAR limits for Normal Operating Mode or for First Level Controlled Operating Mode must be observed for the entire active scan session as follows:
 - Whole body averaged, ≤ 4.0 W/Kg
 - Head, ≤ 3.2 W/Kg
- Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis
- No local transmit-only coils or local transmit/receive coils placed directly over the pacing system; the use of receive-only coils is not restricted
- Patient in supine or prone position only
- Patient must be monitored during the MRI scan by pulse oximetry and/or electrocardiography (ECG)

All trademarks are the property of their respective owner.

1. Please refer to the MRI Technical Guide: ImageReady™ MR - Pacing System as the system is designated as MR-conditional in accordance with specific conditions.

Pacing Systems from Boston Scientific: ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™

INDICATIONS AND USAGE: Boston Scientific pacemakers are indicated for treatment of the following conditions:

- Symptomatic paroxysmal or permanent second- or third-degree AV bloc
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.

Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
- Low cardiac output or congestive heart failure secondary to bradycardia

CONTRAINDICATIONS: These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.

Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed:

- Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
- Minute Ventilation in patients with both unipolar atrial and ventricular leads
- Single-chamber atrial pacing in patients with impaired AV nodal conduction
- Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing
- Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

WARNINGS: General Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize.

Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

PRECAUTIONS: For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

POTENTIAL ADVERSE EVENTS: Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. A)

Pacing Leads from Boston Scientific –INGEVITY™ MRI Extendable/Retractable Fixation and Tined Fixation

INDICATIONS INGEVITY™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only preformed atrial J with the Tined Fixation) and/or right ventricle (only straight with the tined fixation) when used with a compatible pulse generator.

CONTRAINDICATIONS Use of these leads are contraindicated in: patients with a hypersensitivity to a nominal single dose dexamethasone acetate: 0.61 mg for Tined Fixation, 0.91 mg for Extendable Retractable Fixation; and patients with mechanical tricuspid heart valves.

WARNINGS: Refer to the product labeling before implanting the lead to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. Implant of the system cannot be performed in an MRI site Zone III (and higher). Take care to obtain appropriate electrode position. Failure to do so may result in suboptimal lead measurements. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

For Extendable/Retractable Fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

Precautions: Refer to the implant product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing of the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Defibrillation equipment should be kept nearby during the implant procedure. Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.

For Extendable/Retractable Fixation: Avoid creating sharp bends while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil or fixation mechanism during helix extension or retraction. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

Potential Adverse Events: Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Refer to the physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events.

Rx only. (Rev. A)

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Rhythm Management

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Patients and Families:
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